AzPA

Arizona Pharmacy Association

COVID-19 TOWN HALL

September 16, 2020

Agenda

- COVID-19 State and National Updates
- Q & A
- Immunization Updates (Flu and COVID-19)
- Q & A

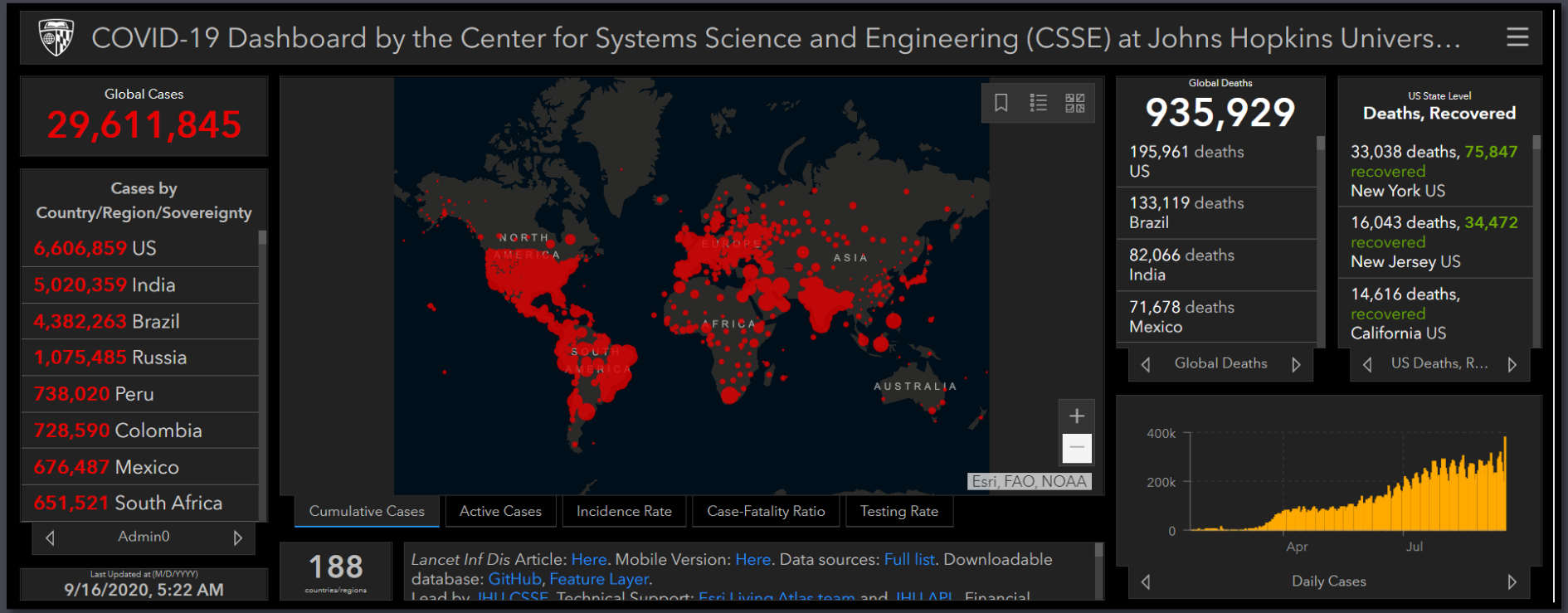
State and National Updates

Kelly Fine

Executive Director | Arizona Pharmacy Association

Worldwide Cases

JOHNS HOPKINS UNIVERSITY & MEDICINE | CORONAVIRUS RESOURCE CENTER



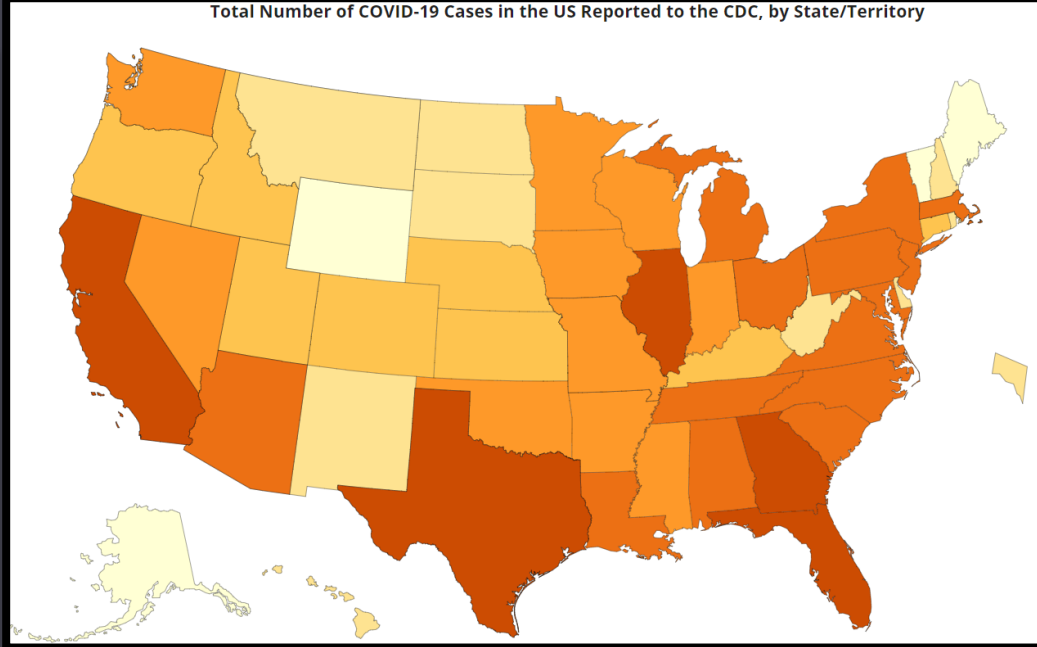
National Cases

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

USA
6,537,627
TOTAL CASES
+34,597 Cases since yesterday
CDC | Updated: Sep 15 2020 12:16PM

USA
194,092
TOTAL DEATHS
+387 Deaths since yesterday
CDC | Updated: Sep 15 2020 12:16PM

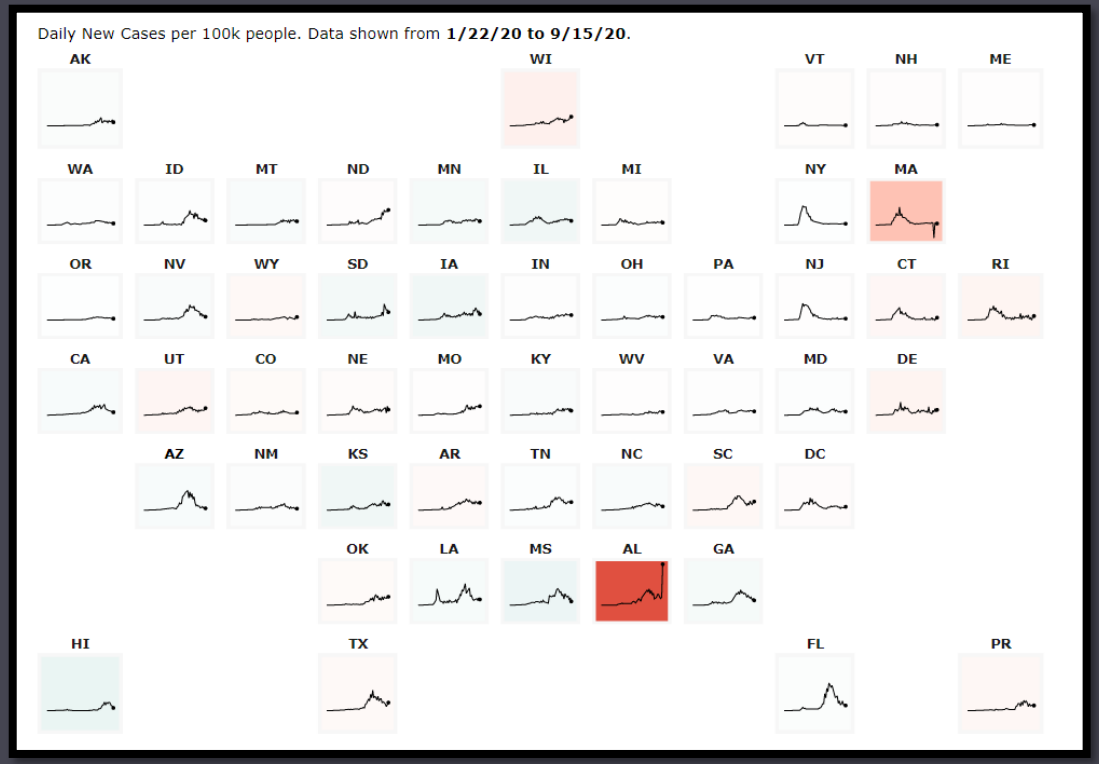
USA
250,265
Cases in Last 7 Days
CDC | Updated: Sep 15 2020 12:16PM

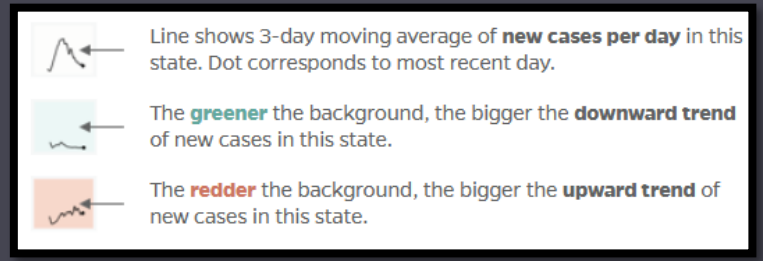


Total Cases by State/Territory

State/Territory	Total Cases	Confirmed	Probable
California	757,778	N/A	N/A
Texas	663,445	N/A	N/A
Florida	658,203	N/A	N/A
Georgia	295,337	N/A	N/A
Illinois	264,839	262,744	2,095
New York City*	239,289	233,972	5,317
Arizona	208,725	206,775	1,950
New York*	206,881	N/A	N/A
New Jersey	196,968	N/A	N/A
North Carolina	185,781	N/A	N/A
Tennessee	174,274	169,130	5,144
Louisiana	158,882	N/A	N/A
Pennsylvania	145,063	140,842	4,221
Alabama	139,459	126,299	13,160
Ohio	138,484	131,235	7,249
Virginia	135,514	129,259	6,255
Massachusetts	133,035	123,139	9,896
South Carolina	132,680	130,256	2,424
Michigan	124,287	112,612	11,675
Maryland	117,245	N/A	N/A
Indiana	106,540	N/A	N/A
Missouri	104,079	N/A	N/A

Daily confirmed new cases (3-day moving average)





ARIZONA DEPARTMENT OF HEALTH SERVICES
Health and Wellness for All Arizonans

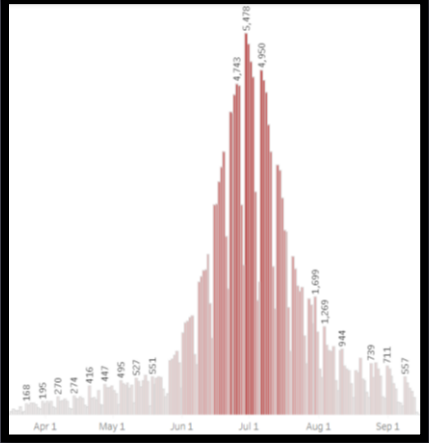
Arizona

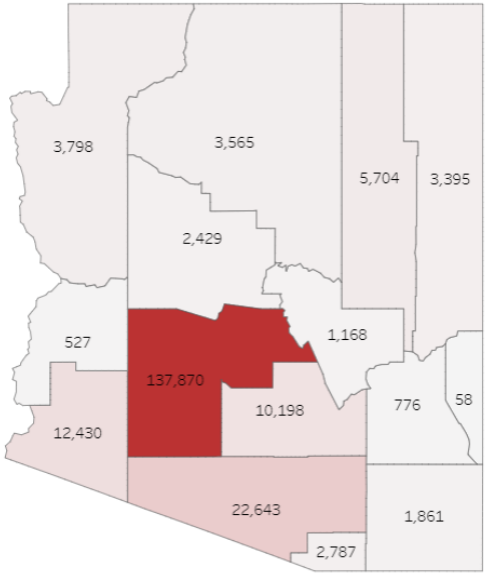
9/2/20: 0.81
9/9/20: 0.92

Current R_t	Cases	Tests
1.01	**208,723**	**1,300,635**

COVID-19 Cases by Day

Date of specimen collection is used for day





Number of Cases	Number of Deaths	Number of COVID-19 Tests
209,209	5,344	1,588,790

Number of New Cases reported today*	Number of New Deaths reported today*	Number of New Tests reported today*
484	22	10,097

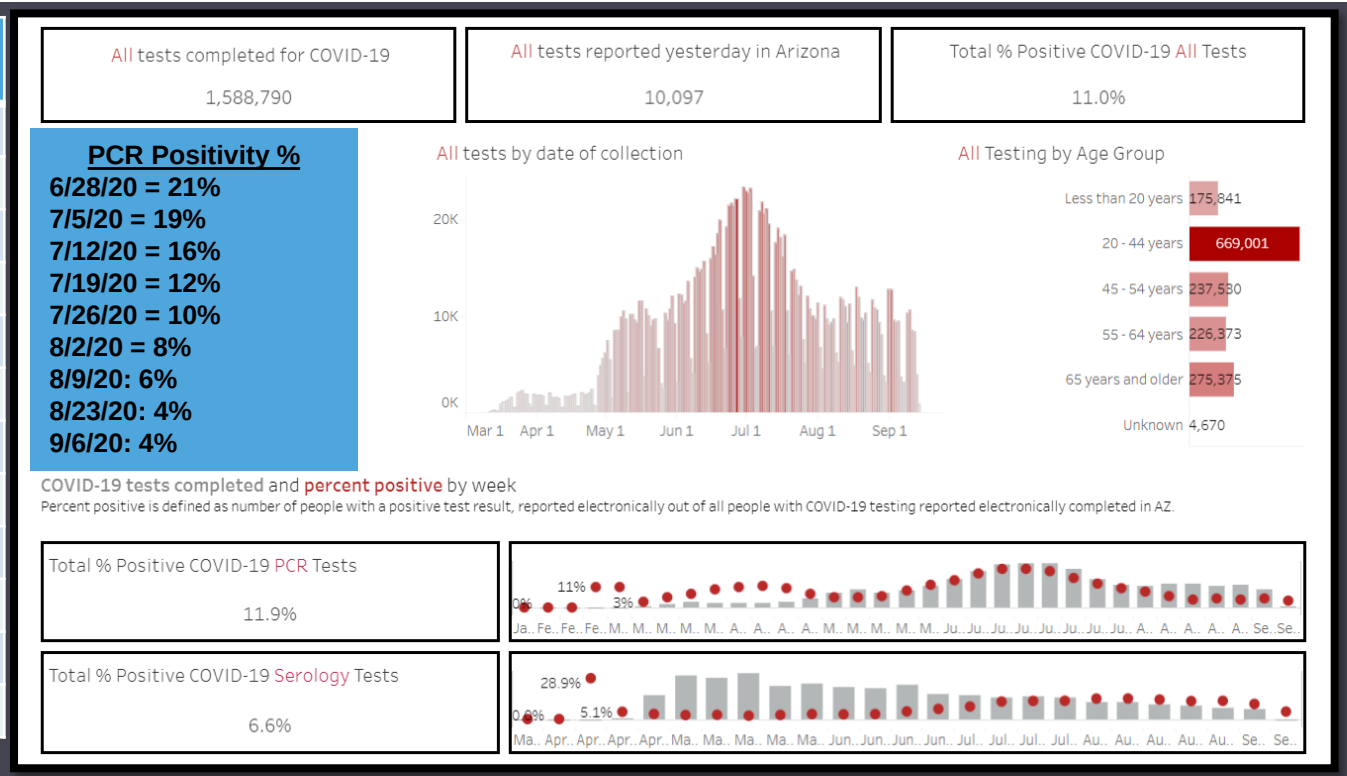
Rate of cases, per 100,000 population	Rate of fatalities, per 100,000 population	Total Percent Positive**
2,910.1	74.34	11.0%

Total COVID-19 PCR Tests	New PCR Tests reported today*	PCR Percent Positive**
1,310,315	9,651	11.9%

Total COVID-19 Serology Tests	New Serology Tests reported today*	Serology Percent Positive**
278,475	446	6.6%

Laboratory Testing

Date	Total % Positive	PCR % Positive	Sero % Positive
6/17/20	7.1%	8.7%	3.1%
6/24/20	8.6%	10.5%	3.0%
7/1/20	9.9%	12%	3.2%
7/8/20	11.3%	13.6	3.4%
7/15/20	11.9%	14.2%	3.7%
7/22/20	12.4%	14.6%	4.4%
7/29/20	12.7%	14.6%	4.9%
8/5/20	12.6%	14.4%	5.3%
8/11/20	12.4%	13.9%	5.7%
9/1/20	11.5%	12.6%	6.4%
9/8/20	11.2%	12.2%	6.5%
9/15/20	**11%**	**11.9%**	**6.6%**



Hospitalizations

ARIZONA DEPARTMENT OF HEALTH SERVICES
Health and Wellness for All Arizonans

INPATIENT BED USE		
Date	**Total (in use %)**	**# COVID**
6/15/20	6,231 (81%)	1,506
6/22/20	6,469 (83%)	2,136
6/29/20	6,488 (85%)	2,793
7/6/20	6,472 (82%)	3,356
7/13/20	6,721 (85%)	3,517
7/20/20	6,636 (83%	3041
7/27/20	6,386 (81%)	2564
8/3/20	6,487 (81%)	2024
8/11/20	6,476 (81%)	1469
8/31/20	6435 (81%)	729
9/7/20	6300 (79%)	657
9/14/20	**6352 (80%)**	**550**

ICU BED USE		
Date	**Total ICU (in use%)**	**# COVID**
6/15/20	1,307 (80%)	502
6/22/20	1,412 (84%)	614
6/29/20	1,435 (86%)	683
7/6/20	1,481 (90%)	869
7/13/20	1,498 (88%)	970
7/20/20	1,448 (85%)	865
7/27/20	1,433 (84%)	814
8/3/20	1443 (83%)	638
8/11/20	1378 (80%)	510
8/31/20	1289 (77%)	253
9/7/20	1265 (76%)	212
9/14/20	**1294 (78%)**	**138**

VENTILATORS IN USE		
Date	**Total Vents. (in use%)**	**# COVID**
6/15/20	707 (38%)	340
6/22/20	716 (41%)	386
6/29/20	773 (45%)	455
7/6/20	895 (51%)	544
7/15/200	996 (52%)	674
7/20/20	952 (49%)	608
7/27/20	920 (47%)	574
8/3/20	795 (41%)	474
8/11/20	679 (36%)	346
8/31/20	556 (30%)	150
9/7/20	541 (29%)	112
9/14/20	**460 (25%)**	**76**

ADHS School Benchmarks

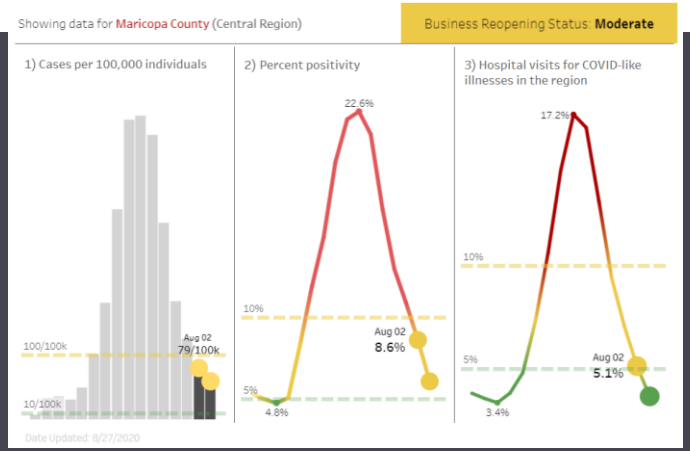
Benchmarks	Minimal	Moderate	Substantial
Cases	<10 cases/100,000	10-100 cases/100,000	>100 cases/100,000
Percent Positivity	<5%	5-10%	>10%
COVID-like Illness	<5%	5-10%	>10%

Community Spread Level	Delivery Model	Hand Hygiene & Respiratory Etiquette	Enhanced Cleaning	Proper Ventilation (buildings and Buses)	Monitor Absenteeism	Symptom Screening	Physical Distancing (6 feet)	Cloth Face Coverings	Cohorting	Field Trips & Large Gatherings Canceled	Communal Spaces Closed
No to Minimal	Traditional	x	x	x	x						
Minimal to Moderate	Hybrid	x	x	x	x	x	x	x	x	x	x
Substantial	Virtual w/ onsite support services	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

8/27/20: 3/15 counties were ranked minimal
9/3/20: 10/15 counties are ranked minimal
9/10/20: 10/15 counties are ranked minimal

	Cases	% Positivity	CLI*
Apache	✔	✔	✔ (Northern Region)
Cochise	✔	✔	✔ (Southern Region)
Coconino	✔	✔	✔ (Northern Region)
Gila	✘	✘	✔ (Central Region)
Graham	✘	✘	✔ (Southern Region)
Greenlee	✔	✔	✔ (Southern Region)
La Paz	✔	✔	✔ (Western Region)
Maricopa	✔	✔	✔ (Central Region)
Mohave	✔	✘	✔ (Western Region)
Navajo	✔	✔	✔ (Northern Region)
Pima	✔	✔	✔ (Southern Region)
Pinal**	✘	✔	✔ (Central Region)
Santa Cruz	✔	✔	✔ (Southern Region)
Yavapai	✔	✔	✔ (Northern Region)
Yuma	✔	✘	✔ (Western Region)

ADHS Phased Reopening-Businesses



Category	Counties
Substantial	Gila, Graham, Yuma
Moderate	Apache, Cochise, Coconino,, Maricopa, Mohave, Navajo, Pima, Pinal, Santa Cruz, Yavapai
Minimal	Greenlee, La Paz

BENCHMARKS	Minimal	Moderate	Substantial
CASES	<10 cases/100,000	10-100 cases/100,000	>100 cases/100,000
PERCENT POSITIVITY	<5%	5-10%	≥10%
COVID LIKE ILLNESS	<5%	5-10%	>10%

BENCHMARKS	Minimal	Moderate	Substantial
Gyms	50% occupancy, must continue to implement ADHS mitigation requirements until < 3% positivity	25% occupancy, must implement ADHS mitigation requirements	Closed
Movie Theaters, Water Parks and Tubing	50% occupancy, must continue to implement ADHS mitigation requirements until < 3% positivity.	50% occupancy, must implement ADHS mitigation requirements	Closed
Bars and nightclubs that have a food establishment permit	50% occupancy, only if converted to restaurant service per ADHS mitigation requirements until < 3% positivity. Once < 3% positivity, 50% occupancy operating as a bar with ADHS mitigation requirements.	50% occupancy, only if converted to restaurant service per ADHS mitigation requirements. Encourage outdoor dining	Closed
Bars and nightclubs without a food establishment permit	Closed until 3% positivity. Once 3% positivity, operate at 50% occupancy with ADHS mitigation requirements.	Closed	Closed

LTCF-Visitor Restrictions

Follow visitation recommendations based on the **county level** of community spread

Benchmarks	Minimal	Moderate	Substantial
Cases	<10 cases/100,000	10-100 cases/100,000	>100 cases/100,000
Percent Positivity	<5%	5-10%	≥10%
COVID Like Illness	<5%	5-10%	>10%

Community Spread Level	Compassionate Care Visitation	Limited Outdoor Visitation	Limited Indoor Visitation	Symptom Screening of all Visitors	Cloth Face Covering Required	Physical Distancing (6 feet)	Cohorting	Communal Spaces Closed
Minimal	x	x	x	x	x	x		
Moderate	x	x	N/A	x	x	x	x	x
Substantial	x	N/A	N/A Except that ombudsman must be able to visit	N/A	N/A	N/A	N/A	N/A

ADHS COVID-19 Guidance for Visitation at Congregate Settings for Vulnerable Adults and Children

CMS Nursing Home Reopening Recommendations for State and Local Officials

LTCF Update – Visitor Restrictions

Caveat: indoor visits can occur if all the following are met **regardless** of the level of community spread

Facilities in any stage shall allow indoor visits if all the following conditions are met:

- ☑ The visitor presents the facility a negative COVID test (either PCR or antigen) less than 48 hours old.
- ☑ The visitor signs an attestation that they have isolated in the time between the sample was taken and the visit and is free from symptoms.
- ☑ The facility limits contact as much as possible, including a dedicated visitation space.
- ☑ The facility requires mask-wearing by residents (when safe), visitors, and staff.
- ☑ The facility requires hand sanitizing before the visit.
- ☑ The facility maintains a visitor log for contact tracing purposes.
- ☑ The facility institutes enhanced cleaning and sanitation of the facility where the visits occur.

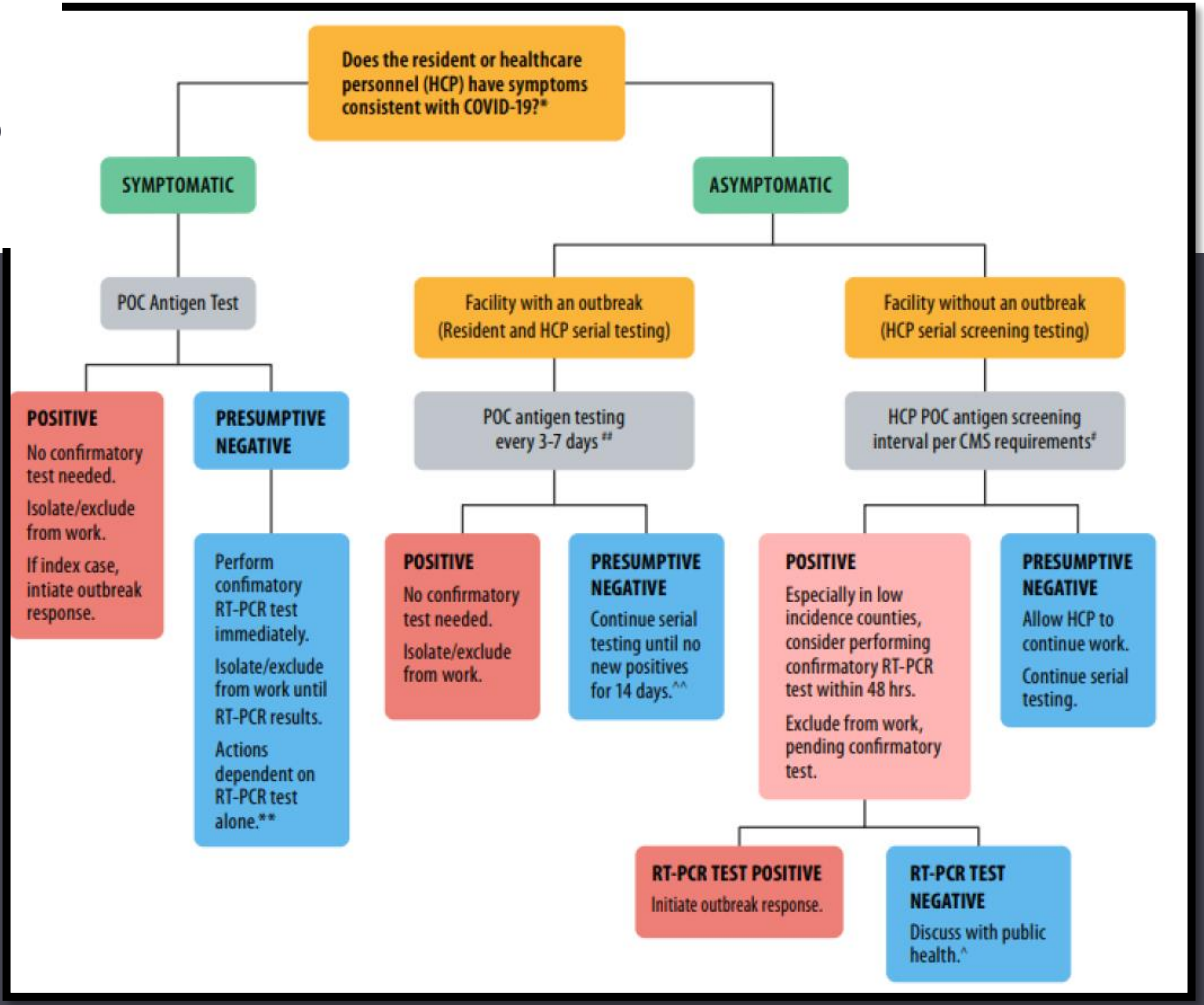
Testing in LTCF's With POC Machines

- Updated MCDPH LTCF Guidance- Coming Soon
- Public Health can assist facilities with testing, if needed (POC test kits, PCR testing etc.)

<u>3 Options For Reporting POC Tests to ADHS:</u>

- Electronic Laboratory Reporting
- Flat file (CSV) submission through secure file transport protocol
- Web entry (manual through Google Forms)

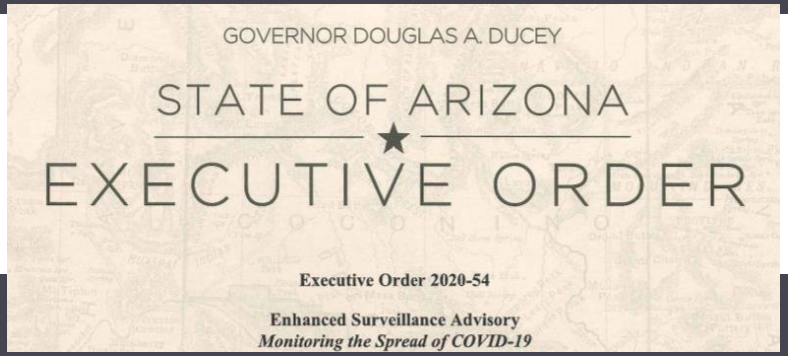
All positive and negative tests need to be reported with 24 hours



Maricopa County Serosurvey

- From September 12-20, 2020 Maricopa County Department of Public Health and Arizona State University will visit randomly selected homes in Maricopa County to invite residents to participate in a CASPER serosurvey, which includes questions about their health and giving a sample for an antibody test.
- Participation will play an important role in helping public health know how many people in Maricopa County have been infected with COVID-19 and how many people need to get vaccinated so we can relax social distancing and mask requirements and get back to a more normal existence.

- They are running extremely low on Nurses/Phlebotomists and field interviewers
- Critical need for Thursday –Sunday (Multiple shifts available)
- Please follow this link to register



- Hospitals must report the following every 24 hours:
  - Line list of all COVID-19 confirmed patients with demographic information
  - Operating in conventional, contingency, or crisis care
  - Number of non-essential surgeries performed per day

- Hospitals must report the following every 24 hours:
  - Number of inpatient flu positive patients or patients with suspected flu
    - Number of ventilators in use by these patients
    - Number of ICU beds in use by these patients
  - Number of flu positive patients or patients with suspected flu seen in the ED per day

Covid-19 Vaccine Trial Participant Had Serious Neurological Symptoms

AstraZeneca paused its COVID-19 trials after a U.K. woman who received the candidate vaccine developed serious neurological symptoms. The participant's presumed diagnosis of transverse myelitis—a spinal inflammatory disorder—is unconfirmed, but her condition has improved enough to consider hospital discharge.

The shutdown is the second since trials began. The trial previously was put on hold in July, also due to neurological symptoms in a single patient, but resumed once the issue was attributed to multiple sclerosis and not the vaccine.

Stopping a clinical trial to investigate a single serious adverse event is not unusual, according to NIH Director Francis Collins.

CLICK HERE

Questions | COVID-19

Immunization Update

Kelly Fine | CEO- Arizona Pharmacy Association

HHS Order #1

FOR IMMEDIATE RELEASE
August 19, 2020

Contact: HHS Press Office
202-690-6343
media@hhs.gov

HHS Expands Access to Childhood Vaccines during COVID-19 Pandemic

The U.S. Department of Health and Human Services (HHS) issued a third amendment - PDF* to the Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) to increase access to lifesaving childhood vaccines and decrease the risk of vaccine-preventable disease outbreaks as children across the United States return to daycare, preschool and school.

"Today's action means easier access to lifesaving vaccines for our children, as we seek to ensure immunization rates remain high during the COVID-19 pandemic," said HHS Secretary Alex Azar. "The Trump Administration has worked to allow pharmacists—alongside all of America's heroic healthcare workers—to practice at the top of their license, empowering the public with more options to protect their health and well-being."

The amendment authorizes State-licensed pharmacists (and pharmacy interns acting under their supervision to administer vaccines, if the pharmacy intern is licensed or registered by his or her State board of pharmacy) to order and administer vaccines to individuals ages three through 18 years, subject to several requirements:

- The vaccine must be approved or licensed by the Food and Drug Administration (FDA).
- The vaccination must be ordered and administered according to the CDC's Advisory Committee on Immunization Practices (ACIP) immunization schedules.
- The licensed pharmacist must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.
- The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.
- The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.
- The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period.
- The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine.
- The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregivers accompanying the children of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate.

HHS Order #2

FOR IMMEDIATE RELEASE
September 9, 2020

Contact: OASH Press Office
202-205-0143
ashmedia@hhs.gov

Trump Administration Takes Action to Expand Access to COVID-19 Vaccines

Today, under the leadership of President Trump, the U.S. Department of Health and Human Services (HHS), through the Assistant Secretary for Health, issued guidance under the Public Readiness and Emergency Preparedness Act (PREP Act) to expand access to safe and effective COVID-19 vaccines when they are made available. This guidance authorizes state-licensed pharmacists to order and administer, and state-licensed or registered pharmacy interns acting under the supervision of the qualified pharmacist to administer, COVID-19 vaccinations to persons ages 3 or older, subject to certain requirements.

"This action builds upon our Administration's progress toward delivering a safe, effective, and widely available vaccine by 2021," said Assistant Secretary for Health ADM Brett P. Giroir, M.D. "Allowing pharmacists to order and administer COVID-19 vaccines will greatly expand convenient access for the American people."

To qualify as "covered persons" under 42 U.S.C. § 247d-6d((i)(8)(B) when administering COVID-19 vaccines authorized or licensed by the U.S. Food and Drug Administration (FDA) to persons ages 3 or older, state-licensed pharmacists and pharmacy interns licensed or registered by their state board of pharmacy must satisfy the following requirements:

- The vaccine must be FDA-authorized or FDA-licensed.
- The vaccination must be ordered and administered according to the Advisory Committee on Immunization Practices' (ACIP) COVID-19 vaccine recommendation.
- The licensed pharmacist must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.
- The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE.
- The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic CPR.
- The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each state licensing period.
- The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including reviewing the vaccine registry or other vaccination records prior to administering a vaccine.
- The licensed pharmacist must, if the patient is 18 years of age or younger, inform the patient and the adult caregiver accompanying the patient of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and refer patients as appropriate.
- The licensed pharmacist and the licensed or registered pharmacy intern must comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s).

The authorization preempts any state and local laws that prohibit or effectively prohibits those who satisfy these requirements from ordering or administering COVID-19 vaccines as set forth above. The authorization does not preempt state and local laws that permit additional individuals to administer COVID-19 vaccines to additional persons.

Well Child Templates

Date **xx/xx/200x**

Letter

Dear **Name of Patient**,

You have taken an important step in protecting your child and your family from infectious disease through vaccination. Your pharmacist is an important part of your health care team and strives to collaborate with other team members to best meet your child's individual healthcare needs. Just as your pharmacist provides important services related to your and your child's medications and overall health, having a primary care provider is also important. A primary care provider oversees your child's overall health and well-being.

As children develop, well-child visits with your child's primary care provider provide a time to review and discuss each of the important areas of your child's development, including physical, cognitive, emotional, and social development. A trusting, ongoing relationship with a primary care provider, ensures that your child's health and medical needs will be identified and addressed. Your child's primary care provider can monitor your child's health and development and suggest changes to help prevent serious illness. Well-child visits are a way to foster development of optimal physical, mental and social health for your child, and coordinate y tests, checkups and follow-up care.

Ask your pharmacist for advice in finding a primary care provider in your community if you do not currently have one.

[Pharmacist]

Referral Form

Referral Form for Well-Child Visit

Patient Name (First/Last): _____

Referring Pharmacist: _____ email: _____

Pharmacy Practice: _____ Phone Number: _____

FAX Number: _____

Email: _____ Date of Referral: _____

Signature: _____ **Date:** _____

The above patient was seen in our pharmacy/practice today and the following vaccines administered. The patient was informed regarding the importance of well-child visits. Additional items needing potential follow-up are indicated below. Feel free to contact us if you have further questions. We would appreciate receiving an update after you have seen the patient so that we can update our records and support your treatment plan. We have submitted the vaccines we gave today in the state/local immunization information system (IIS).

Reason for Referral: ☐ **Well-child checkup** ☐ **Other follow-up**

The following vaccine(s) were administered today:	**Patient may need additional immunization(s)**
❑ DTaP	❑ _____
❑ Hep A	❑ _____
❑ Hep B	❑ _____
❑ Hib	**Comment:**
❑ HPV	
❑ Influenza	
❑ MMR	
❑ Meningococcal	
❑ Pneumococcal (PCV)	
❑ Polio (IPV)	
❑ Rotavirus	
❑ Td / Tdap	
❑ Varicella	
❑ Other: _____	

DRAFT

Brochure

Importance of Well Child Visits –
Keeping Your Kids Healthy

It is important to get a personal primary care provider and to use the same practitioners as much as possible for your child's healthcare needs. The members of your child's healthcare team, that incudes primary care providers, pharmacists and other healthcare professionals, are focused on the well-being of your child. A personal primary care provider:

- Helps you get care for your child
- Provides care when your child is sick
- Knows your child's medical history and the family history
- Keeps track of your child's medical services, such as immunizations (shots)
- Can give you important information about your child's growth and development
- Refers your child to a specialist when needed
- Helps to coordinate your child's health needs

Well child visits are important, even when children are healthy. Well child visits will help to keep your child healthy. Your child's primary care provider will evaluate your child's general health, growth and development. Your child's primary care provider will also give you information and give your child needed medical services, such as:

- Health exams
- Tests, such as vision, hearing and lab services
- Shots (vaccinations)
- Lead screening (children under 3 years or as needed for older children)
- Tracking growth and development
- Medical referrals to specialists, if needed

With the help of regular well child visits, your child's primary care provider can often detect and address health problems before they become more serious.

Your children's primary care provider will review your child's health and family history. Well child visits let you and your child get to know the primary care provider and they can get to know you and your child. They will also maintain keep your child's medical record and coordinate care with other members of your child's healthcare team, including your pharmacist.

Well-Child Visit Brochure (PDF)
Template Referral Form Well-Child Visit (Word)
Well-Child Checkup Letter (Word)

AHCCCS Pharmacy Flu Plan

- Pharmacies will NOT have to enroll in VFC to administer Flu Vaccine to AHCCCS members.
- You will bill the MCO's as you currently do for adult vaccines once the updates have been made.
  - Members are required to use a pharmacy that is in the member's MCO's Pharmacy Network.
  - All AHCCCS registered pharmacies can serve members enrolled with a Fee-for-Service Program, including the American Indian Health Program and Tribal Arizona Long Term Care System.
  - Reimbursement is based on the contract between the specific MCO PBM and the pharmacy.
- $10 Gift Cards will be made available through MCO.

The Arizona Department of Health Services

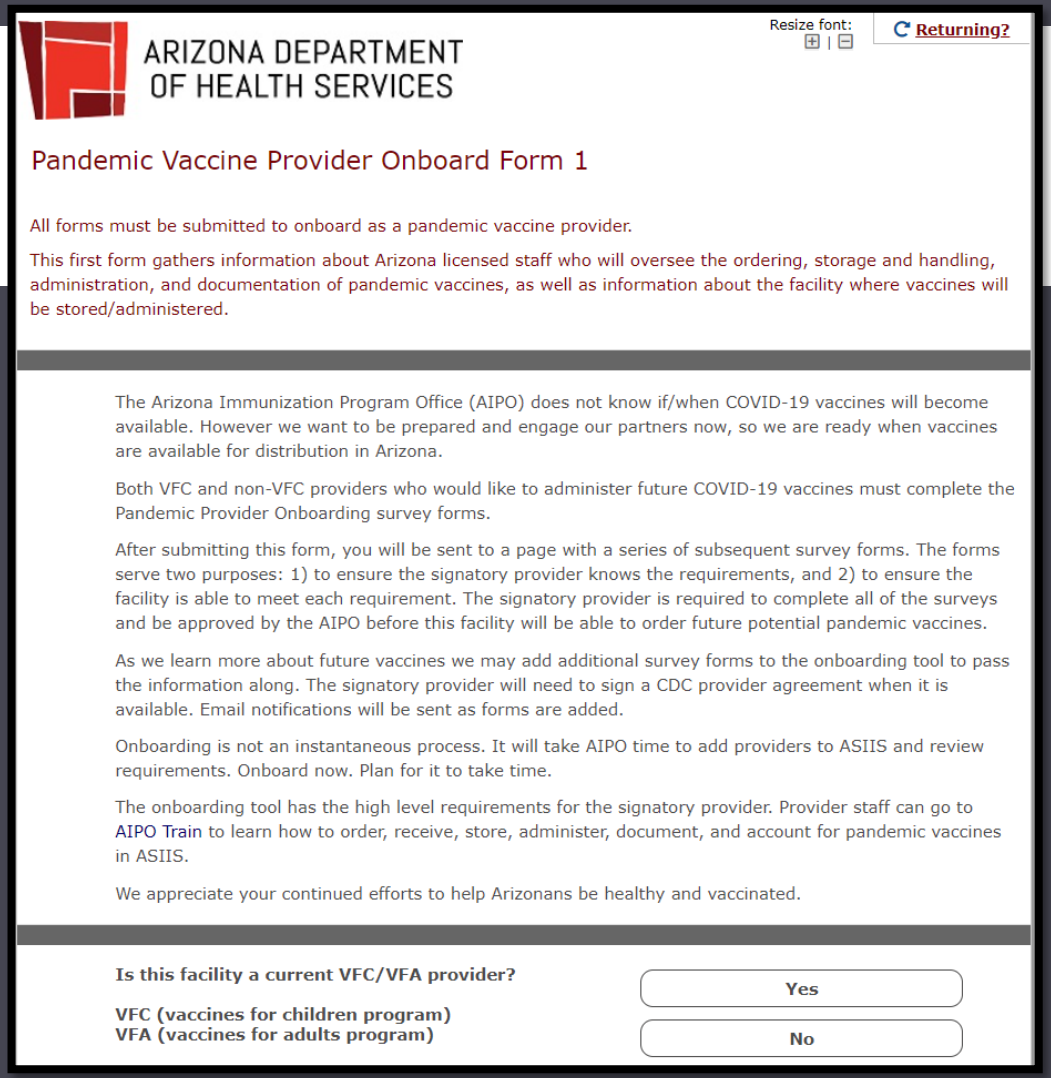
In preparation for concurrent influenza season and COVID-19 pandemic, widespread uptake of influenza vaccine is more important than ever.

- **Register for VaccineFinder** at https://locating.health/register. This will be the primary source that public health uses to alert the public of where to get flu vaccination.
- **Participate in and share** the statewide flu media campaign ROLL UP YOUR SLEEVE and get your flu vaccine. (provides a uniform flu vaccination message statewide).
- **Stay up to date** on the state's case counts on the ADHS flu dashboard and COVID-19 dashboard

Keeping Arizonans safe and out of the hospital will be key during this winter season. Please keep yourself and your patients safe by encouraging your patients to get the flu vaccination.

VaccineFinder and MedFinder

- **VaccineFinder**: Participating pharmacies can update supply estimates for routine adult and child vaccines, and any travel vaccines that they carry.
- **MedFinder:** Participating pharmacies can update their antiviral drug supply.
- **Questions:** locatinghealth@healthmap.org
- **Training**: September 16, 2020 | 2:00PM – 3:00PM ET
  - Register in advance: CLICK HERE



ARIZONA DEPARTMENT OF HEALTH SERVICES

Resize font: | Returning?

Pandemic Vaccine Provider Onboard Form 1

All forms must be submitted to onboard as a pandemic vaccine provider.

This first form gathers information about Arizona licensed staff who will oversee the ordering, storage and handling, administration, and documentation of pandemic vaccines, as well as information about the facility where vaccines will be stored/administered.

The Arizona Immunization Program Office (AIPO) does not know if/when COVID-19 vaccines will become available. However we want to be prepared and engage our partners now, so we are ready when vaccines are available for distribution in Arizona.

Both VFC and non-VFC providers who would like to administer future COVID-19 vaccines must complete the Pandemic Provider Onboarding survey forms.

After submitting this form, you will be sent to a page with a series of subsequent survey forms. The forms serve two purposes: 1) to ensure the signatory provider knows the requirements, and 2) to ensure the facility is able to meet each requirement. The signatory provider is required to complete all of the surveys and be approved by the AIPO before this facility will be able to order future potential pandemic vaccines.

As we learn more about future vaccines we may add additional survey forms to the onboarding tool to pass the information along. The signatory provider will need to sign a CDC provider agreement when it is available. Email notifications will be sent as forms are added.

Onboarding is not an instantaneous process. It will take AIPO time to add providers to ASIIS and review requirements. Onboard now. Plan for it to take time.

The onboarding tool has the high level requirements for the signatory provider. Provider staff can go to AIPO Train to learn how to order, receive, store, administer, document, and account for pandemic vaccines in ASIIS.

We appreciate your continued efforts to help Arizonans be healthy and vaccinated.

Is this facility a current VFC/VFA provider?

VFC (vaccines for children program)
VFA (vaccines for adults program)

Yes

No

If you work for a chain pharmacy please talk to your supervisor first

Every pharmacy who wants vaccine will need to complete the Pandemic Provider Onboarding survey for each location.

You do not have to be a VFC provider to order COVID vaccine but will require many of the same requirements.

Enter the information for the AZ licensed healthcare provider who will sign this pandemic agreement and be responsible for overseeing staff training, ordering, storage and handling, administering, and accounting for the pandemic vaccine.

First name

Enter the first name as it appears on the AZ medical license

Last name

Enter the last name as it appears on the AZ medical license

Job title

AZ License type

The signing provider in a group practice must be authorized to prescribe vaccines under state law.

License #

The signing provider in a group practice must be authorized to prescribe vaccines under state law.

National Provider Identifier (NPI)

10 characters remaining

Email address for _____ _____

Confirm email for _____ _____

Phone number for _____ _____

Phone extension

Primary Vaccine Coordinator

First name

Last name

Job title

Email for _____ _____

Confirm email for _____ _____

Phone number for _____ _____

Phone extension

Back-up Vaccine Coordinator

First name

Last name

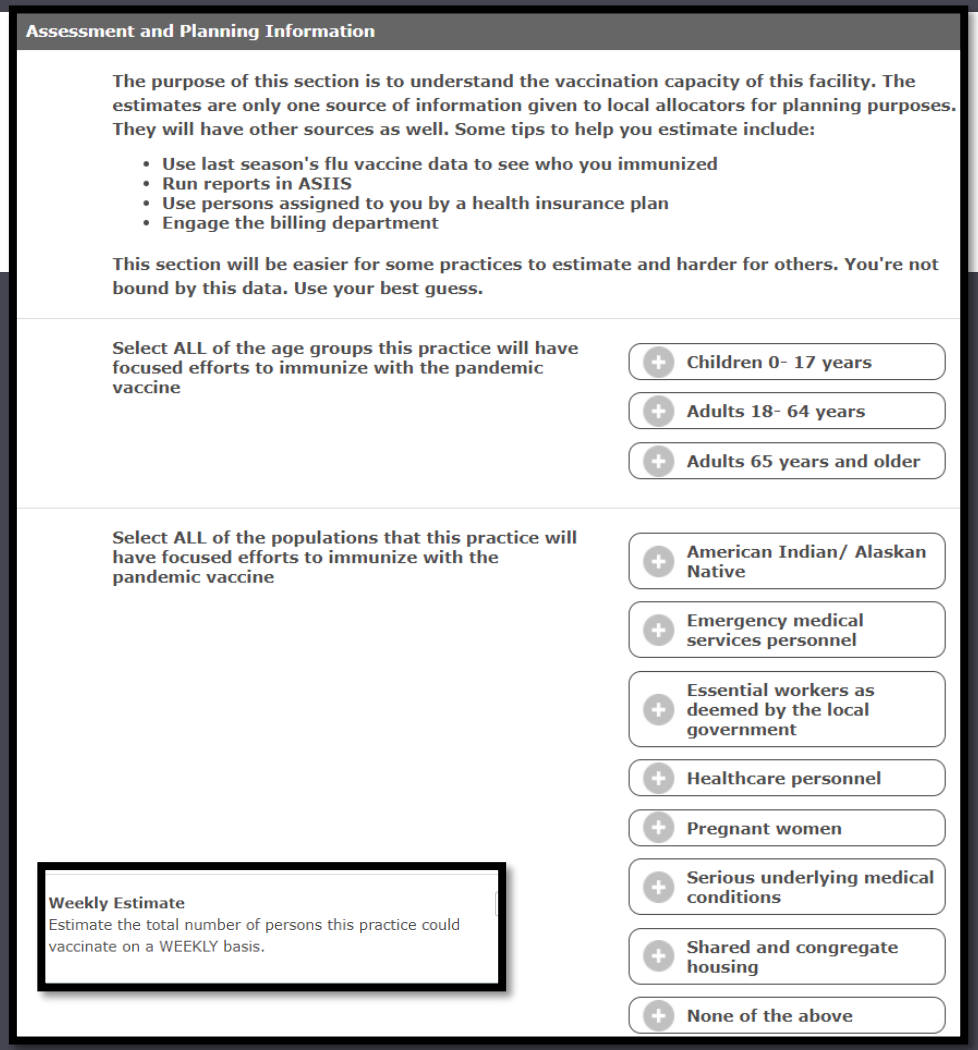
The primary and back-up coordinators must be different people.

Job title

Email address for _____ _____

Confirm email for _____ _____

Phone number for _____ _____



https://redcapaipo.azdhs.gov/surveys/?s=DY8CA9LMJ8

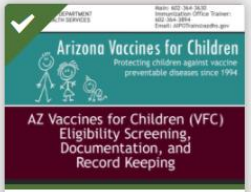
MY COURSES

https://aipo.myabsorb.com/#/signup-form

Date Enrolled

Dose Accountability Webinar
September 22nd
View

ASIIS Inventory Reconciliation
Online Course
Start



Documentation and Record Keeping (Pandemic Providers)
Online Course
Completed

How to Login to ASIIS & Patient Record Management
Online Course
Start

How to Place an Order in ASIIS
Online Course
Start

Mass Immunization (Pandemic Providers)
Online Course
Start

Onboarding Resources (Pandemic Providers)
Online Course
Start

Vaccine Inventory (Pandemic Providers)
Online Course
Completed

Vaccine Storage and Handling (Pandemic Providers)
Online Course
Resume

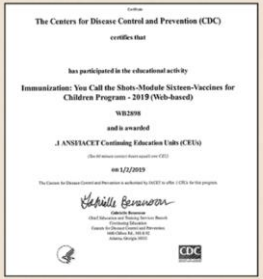
VFC 400 LogTag Data Logger Set Up Instructions & Training
Online Course
Start

VFC 400 LogTag Online User Guide
Online Course
Start

One of the following certificates will need to be on file with the Arizona Immunization Program Office.

AIPO Train

You Call The Shots



TEMPERATURE MONITORING

In order to be approved by The Arizona Immunization Program Office (AIPO) to receive and administer pandemic vaccines, each facility/branch will be required to:

- Monitor the temperatures of the vaccines twice daily using a data logger that meets AIPO requirements
- Have a portable back up data logger readily available
- Download and review the data logger data every two weeks
- Retain the data logger reports and paper temp logs for 6 years
- The facility must submit data logger reports to the AIPO upon request
- If a provider office will be closed for more than four (4) days, someone must come in on the fifth and subsequent days to take the temperatures twice a day or call the Arizona Immunization Program Office (AIPO) to inquire about transporting the vaccine to another provider before the closure occurs. Follow the AIPO transfer policy, which includes getting approval in ASIIS before the transfer occurs

DIGITAL DATA LOGGER REQUIREMENTS

The data logger must be equipped with:

- a temperature probe or sensor in a buffered material (usually glycol). The probe must be kept in the middle of the unit with the vaccines to ensure that the temperature of the air around the vaccines is being recorded
- an active temperature display on the outside of the unit that can be easily read without opening the storage unit door
- continuous temperature monitoring and recording capabilities and the capacity to routinely downloa data

The data logger must have a valid certificate of calibration which includes:

- model/device number
- serial number
- date of calibration (report or issue date)
- confirmation the instrument passed testing (or instrument in tolerance)
- at least one of the following items in regards to the calibration testing: conforms to ISO 17025, was performed by an ILAC/MRA Signatory body accredited Laboratory, is traceable to the standards maintained by NIST, or meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 tolerance Class F (≤ 0.5°C) or better

- Even though the data logger records temperatures, you must also use the paper temperature log to document that you looked at the data logger to monitor the temperatures

Arizona will use ASIIS, the online immunization registry, to order, receive, and account for pandemic vaccines. After the onboarding forms are submitted and approved, the persons listed on the first form will be given ASIIS login accounts if they do not already have one. The ASIIS

Patient Data:

- Patient first and last name
- Patient date of birth
- Patient gender
- Patient address (Street address, City, State, Zip)
- Medical ID number
- Guardian first and last name
- Mother's maiden name
- Multiple Birth Indicator (Y/N) and Multiple Birth Order (1,2,3.
- Administration Route
- Administration Site

Administration data:

Federal law requires providers to document the following data elements in the patient's record:

- The name of the vaccine administered
- The vaccine manufacturer
- The date the vaccine is administered
- The lot number of the vaccine
- The name and title of the person who administered the vaccine
- The address of the clinic where the vaccine was administered
- The Vaccine Information Statement (VIS) publication date located in the lower right corner on the back of the VIS
- The date the VIS is given to the patient, parent, or guardian

Dose Accountability Data:

Providers are required to account for vaccines distributed through the Arizona Immunization Program Office (AIPO) in ASIIS. Inventory decrementation is the key to accounting for doses in ASIIS. When data is transferred from the EMR/EHR to ASIIS, the following data elements must be correct in ASIIS in order for the doses to decrement (deduct) from the ASIIS inventory and be accounted for:

- Funding source: Federal
- Lot number: Must match the lot number on the BOX
- Manufacturer: Must match the manufacturer on the BOX
- Vaccine code (NDC from the box or CVX code)
- ASIIS facility ID

COVID-19 Vaccine Update

HOLLY VAN LEW, PHARM.D., BCPS

SEPTEMBER 15, 2020

Operation Warp Speed (OWS)

- Strategy is to deliver safe and effective vaccines expeditiously WITHOUT COMPROMISING SAFETY
  - Elimination of delays in the study
    - Enrollment in study → data collection/evaluation → review process
  - Multiple processes are occurring "in parallel"
- Enable, accelerate, harmonize, and advise companies developing vaccine
- Leverage full capacity of the government to ensure no technical, logistic or financial hurdles will hinder development

Reference: M Slaoui, M Hepburn. Developing Safe and Effective Covid Vaccines—Operation Warp Speed's Strategy and Approach. NEJM 8.26.20. Accessed online at https://www.nejm.org/doi/full/10.1056/NEJMp2027405

Operation Warp Speed (OWS)

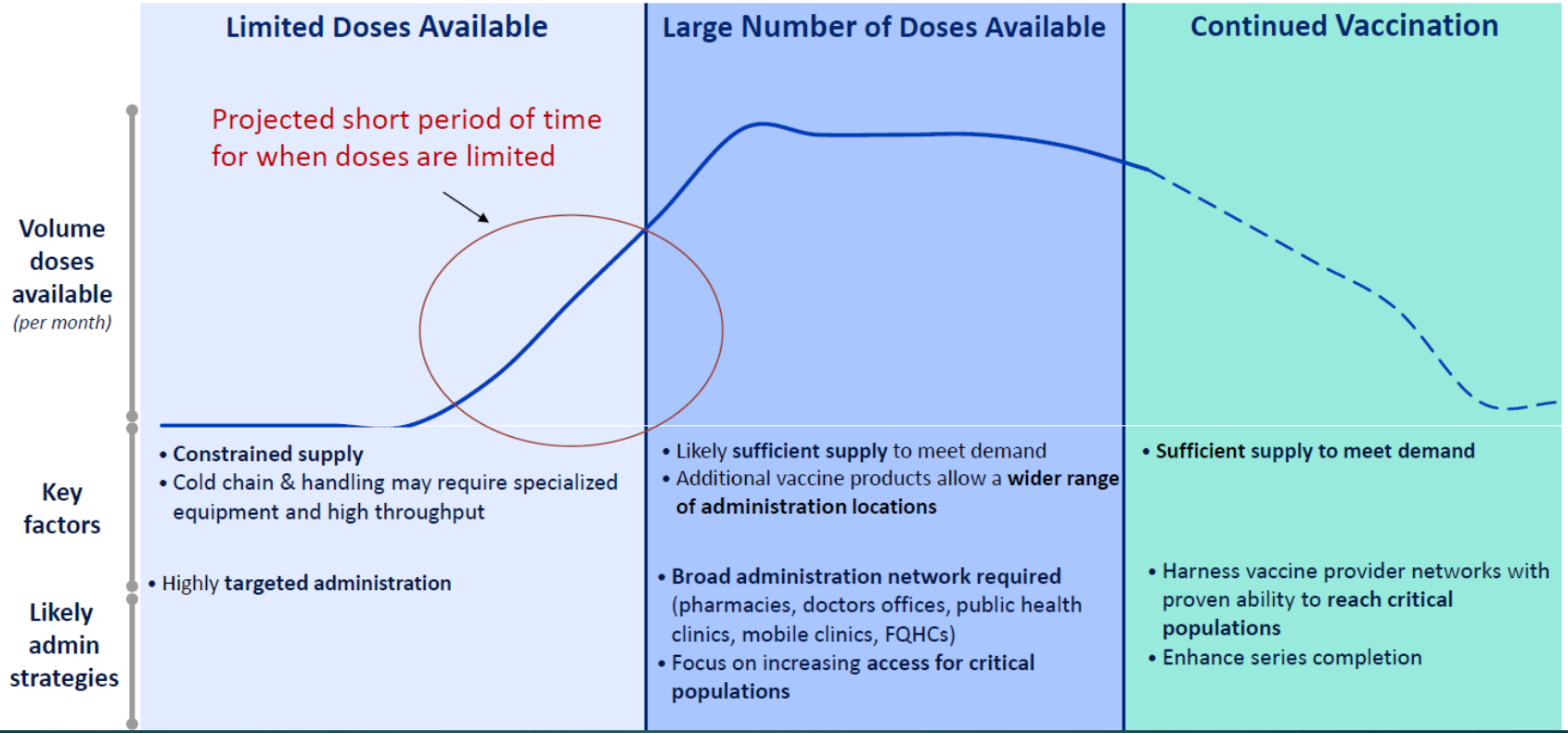
- Collaboration between HHS and DoD
  - National Institutes of Health (NIH)
  - Center for Disease Control and Prevention (CDC)
  - Biomedical Advanced Research and Development Authority (BARDA)
  - Assistant Secretary for Preparedness and Response (ASPR)
- Already manufacturing vaccine
- Planning for distribution if/when vaccine is approved

****Independent FDA safety and efficacy review****

Vaccine Products

- Six front runner vaccines, three fully funded by OWS
  - Several are in Phase 2/3 or Phase 3 clinical trials
- Earliest vaccine (as early as November 2020)
  - Vey limited supply
  - Complex cold chain requirements
    - Ultracold (-80°C) storage
      - CDC IS ADVISING TO **NOT** PURCHASE ULTRACOLD FREEZERS
        - Shipping boxes can accommodate temporary ultracold storage
      - Will require high-throughput mass vaccination events
        - ~1000 to 5000 doses shipped at a time
    - Frozen (-20°C) storage
      - 100 dose minimum

Administration of COVID-19 vaccine will require a phased approach



Knowns

- Novel mechanisms of action
- Most are 2-dose series at 21-28 days
  - Must plan for 2nd dose
- Cannot be co-administered with any other vaccine
- Ultracold (-80°C) & frozen (-20°C) vaccine at earliest phases with some refrigeration time allowed
- Studies only require demonstration of 50% efficacy
- Vaccine well tolerated
  - Fatigue, myalgias, headache reported

For more vaccine information, see ACIP meeting slides

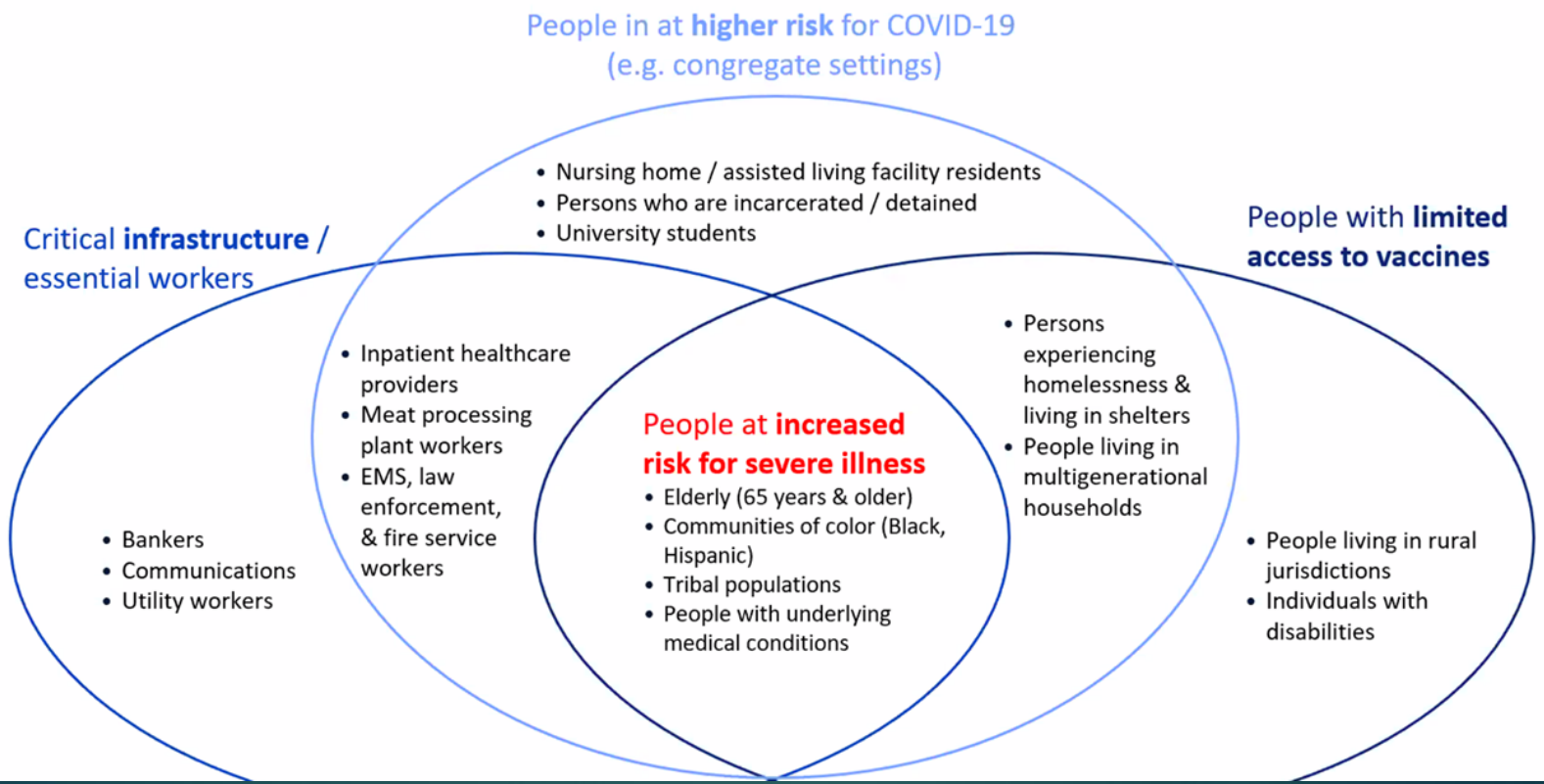
Unknowns

- Duration of action of the vaccines?
- Emergency Use Authorization (EUA) vs. Licensure vs. non-approval
  - EUA may limit who can get the vaccine
  - EUA may require additional monitoring/reporting
- Will there be a minimum wait time between COVID and other vaccines?
- No pediatric or pregnancy data available
- Vaccine effectiveness in special populations

Priority Groups

- Collaboration between:
  - Advisory Committee on Immunization Practices (ACIP)
    - ACIP Meeting 9/22 may solidify priority groups
  - National Academies of Sciences, Engineering and Medicine (NAS)
    - Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine
- Still undetermined at this point - anxiously awaiting info!

Examples of Critical Populations for Targeting Vaccination



Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States

JOHNS HOPKINS
BLOOMBERG SCHOOL
of PUBLIC HEALTH

Tier 1:

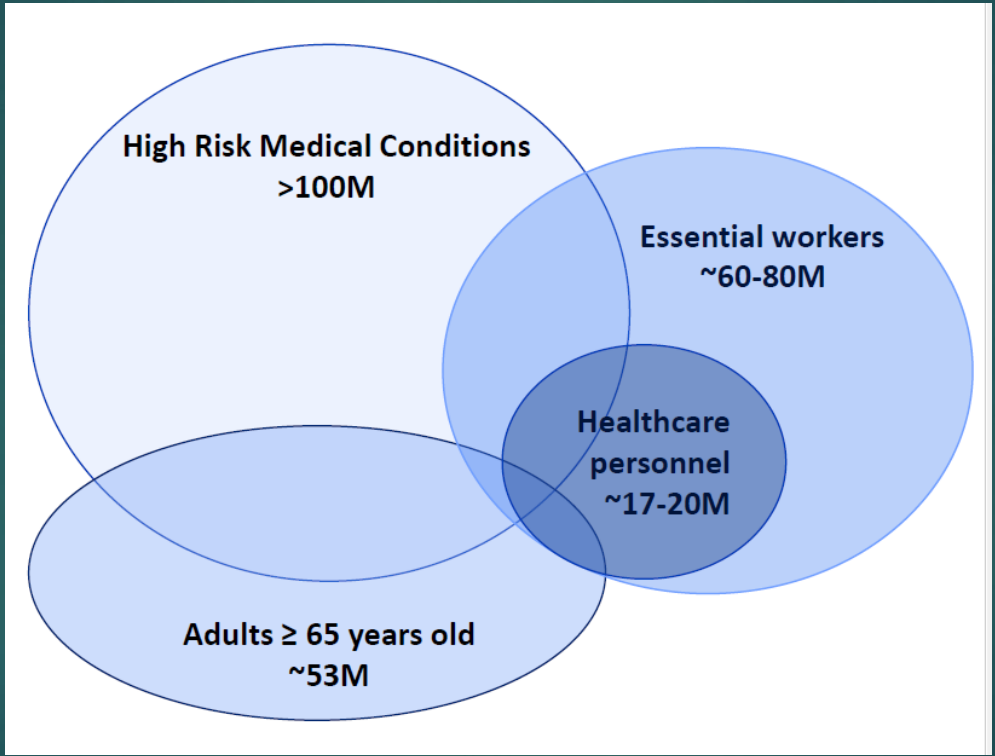
- Those most essential in sustaining the ongoing COVID-19 response
- Those at greatest risk of severe illness and death, and their caregivers
- Those most essential to maintaining core societal functions

Tier 2:

- Those involved in broader health provision
- Those who face greater barriers to access care if they become seriously ill
- Those contributing to maintenance of core societal functions
- Those whose living or working conditions give them elevated risk of infection, even if they have lesser or unknown risk of severe illness and death

"The purpose of this report is to offer an ethics framework that can be used to make decisions about the allocation of a SARS-CoV-2 vaccine during the initial period of scarcity in the United States and make related suggestions about vaccine distribution."

Reference: https://www.centerforhealthsecurity.org/our-work/publications/interim-framework-for-covid-19-vaccine-allocation-and-distribution-in-the-us


High Risk Medical Conditions
>100M
Essential workers
~60-80M
Healthcare
personnel
~17-20M
Adults ≥ 65 years old
~53M

Take Action

Focus	**Focus efforts on influenza vaccination** • Practice social distancing during events • Plan or participate in mass vaccination events • Develop plans for reminder recall
Start	**Start conversations with leadership about COVID planning & consider pre-enrolling with the state**
Consider	**Consider strategies for different vaccine scenarios (ultracold, frozen, capacity, throughput)**
Model	**Model plans after CDC resources that will be forthcoming** • "Playbook" for COVID Pandemic Planning

Take Action

Get Creative	**Get creative and consider novel approaches** • Utilize pharmacy technicians to the fullest level of their licensure • Support pharmacy technician training for vaccine administration
Consider	**Consider solutions for vaccination outside of the pharmacy room**
Identify	**Identify systematic ways to find high-risk individuals**
Recall	**Recall reminder systems – methods/concepts** • Use what we learned from Shingrix shortage

Thank you!

Questions?

Contact info: holly.vanlew@ihs.gov

AzPA 2020 Annual Convention

October 2 - 4, 2020

~~Phoenix, AZ~~ anywhere!

Questions | Immunizations